REMARKS

Applicants respectfully request entry of the Amendment and reconsideration of the claims. Claims 50 and 51 have been amended. Claim 67 has been canceled without prejudice or disclaimer. The specification has been amended to update the priority information. Applicants submit the Amendment is supported throughout the specification, does not raise any issues of new matter, and places the claims in condition for allowance.

Elections/Restrictions

Claim 50 was objected to as encompassing a non-elected invention. In the Restriction Requirement dated June 14, 2006, the Examiner required, with respect to the invention of Group VII, election of a single particular ligand from the group consisting of protein or nucleic acid. While not acquiescing to the objection and solely to expedite prosecution, claim 50 has been amended to recite a nucleic acid encoding a protein or fragment thereof, as elected in Applicants' response to the Restriction Requirement filed July 14, 2006. Withdrawal of the objection is respectfully requested.

Written Description

Claims 50, 51, 53, 63, and 65-67 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

Without acquiescing to the rejection and solely for the purpose of advancing prosecution, Applicants have amended the claims to recite a CHAG nucleic acid comprising SEQ ID NO:9 or CHAG nucleic acid encoding a fragment of a protein encoded by SEQ ID NO:9 wherein the fragment comprises a domain of the protein. Applicants submit the claims as amended are adequately described in the specification. See the specification, for example, at page 12, lines 22-25, page 46, line 19 to page 47, lines 2, and Figure 10. Applicants reserve the right to pursue the canceled subject matter in one or more continuation applications.

Citing *Univ. of Rochester v. G.D. Searle* & Co., 358 F.3d 916, 927 (Fed. Cir. 2004), the Office Action alleges the genus of molecules that bind to a nucleic encoding CH-9 or inhibit expression of CH-9 recited in the claims is not described by a specific biochemical or molecular

structure and that the mere contemplation of the claimed genus in the specification is not sufficient to support the claims. Applicants respectfully do not agree.

Univ. of Rochester does not support the written description rejection as asserted in the Office Action. The claims at issue in *Univ. of Rochester* were reach-through claims drawn to a method of inhibiting PGHS-2 activity in a human host comprising administering to the human host a compound identified by the screening method. In the claims at issue in *Univ. of Rochester*, the compound is used to carry out the claimed methods. See *Univ. of Rochester.*, 358 F.3d at 929. In contrast, Applicants' claims as amended recite methods of identifying molecules or agents that bind a novel ligand or inhibit expression of a novel ligand. The screening method itself, not a genus of molecules that can be screened by the method or a genus of molecules identified by the screening method, is the claimed invention.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. MPEP § 2163(I) (emphasis added). The written description requirement does not require the specification to describe the biochemical or molecular structure of the genus of molecules that can be screened by a novel method or how to make the genus of molecules that can be screened by a novel method. Any molecule can be screened for binding to the recited novel ligand. The Office Action has failed to cite any support for the proposition that an applicant must describe the biochemical or molecular structure of the genus of molecules that could be identified by a screening method. With respect to the claimed screening methods, Applicants submit adequately describing the molecule/ligand (*e.g.*, nucleic acid comprising SEQ ID NO:9) that provides a binding target is all that is required to satisfy the written description requirement.

With respect to claim 51, the Office Action alleges there is variation among species of the claimed genus of antisense nucleic acids and that the mere contemplation of the genus of antisense nucleic acids in the specification is not sufficient to support the claims. Applicants respectfully do not agree.

The written description requirement must be applied in the context of the particular invention and state of the knowledge. *Capon v. Eschar*, 76 USPQ2d 1078, 1084 (Fed. Cir.

2005). In Example 15 of the Revised Written Description Guidelines Training Materials, the USPTO acknowledges:

> The general knowledge in the art is that any full length complement of a target mRNA inhibits the function of the mRNA and is therefore an antisense oligonucleotide. Thus, one of skill in the art would view applicant's disclosure of a coding sequence, with the statement that the invention includes antisense oligonucleotides, as an implicit disclosure that the full-length complement of the disclosed nucleic acid sequence is an antisense oligonucleotide. Guidelines at page 56.
>
> It is generally accepted in the art that oligonucleotides complementary to a messenger RNA, including fragments of the full-length complement, have antisense activity when they match accessible regions of the mRNA. Guidelines at page 57.
>
> The procedures for making oligonucleotide fragments of the complement of a disclosed nucleic acid sequence and procedures for screening for antisense activity are conventional. Guidelines at page 57.
>
> The nucleic acid sequence defines and limits the structure of any effective antisense molecules such that one skilled in the art would be able to immediately envisage members of the genus embraced by the claim. Guidelines at page 58.

It is unnecessary to spell out every detail of the invention in the specification. Only enough must be included to convince a person of skill in the art that the inventor possessed the invention. *Falkner v. Inglis*, No. 05-1234, slip. op. at 14 (Fed Cir. May 26, 2006) (citing *LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.*, 424 F.3d 1336, 1345 Fed. Cir. 2005). Applicants disclose the structure of the sequence (*e.g.* SEQ ID NO:9) and the sequence provides the structure of antisense molecules such that one of skill in the art would be able to immediately envisage members of the genus embraced by the claim. As discussed above, the Guidelines provide that disclosure of a nucleic acid sequence provides written description for antisense molecules.

Considering the high and advanced level of skill in the art of antisense molecules as described and summarized in the USPTO's Written Description Guidelines, Applicants submit one skilled in the art would have recognized that the genus of antisense molecules that inhibit CHAG gene expression were implicitly disclosed as a result of the isolation of SEQ ID NO:9.

The Office Action alleges the skilled artisan cannot envision the detailed structure of the genus of ligands or antisense molecule because conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures disclosed in the specification. See Office Action at page 7. Applicants respectfully do not agree.

An applicant may show possession of an invention by disclosure of sufficiently detailed, relevant identifying characteristics (i.e. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between structure and function, or some combination of such characteristics) that provide evidence that applicant was in possession of the claimed invention. *Enzo Biochem v. Gen-Probe*, 323 F.3d 956, 964 (Fed. Cir. 2002); MPEP § 2163(II)(3)(A)(a). An actual reduction to practice, however, is not required for written description. *Falkner v. Inglis*, No. 05-1324, slip. op. at 13 (Fed. Cir. May 26, 2006); *Univ. of Rochester v. G.D. Searle and Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004). Applicants submit the specification adequately describes the genus of ligands and antisense molecules for the reasons discussed above.

In view of the forgoing, Applicants submit the claims as amended fully comply with the written description requirement of §112, first paragraph. Withdrawal of the rejection is respectfully requested.

Summary

In view of the above amendments and remarks, Applicants respectfully submit the claims are in condition for allowance and request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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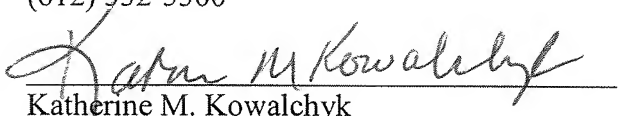
Date: July 20, 2007



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